

KO820912



OCT 15 2008

510(k) Summary

Owner: GaleMed Corporation
97, Li-gong 2nd Road, Wu-jia
I-Lan, Taiwan 268
Tel: + 866 3 990 8618
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Owner/Operator Number: 8043316

Official Contact: Thomas Loescher
Tel: (760) 930-4025
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Trade Names: Resuscitators: 1. DISPO-BAG Manual Resuscitation
2. Bag DISPO-BAG Manual Resuscitation Bag with Disposable PEEP Valve
P.E.E.P. Valve: Disposable PEEP Valve

Common/Usual Name: Resuscitators: 1. Manual Resuscitation
2. Manual Resuscitation Bag with PEEP Valve
P.E.E.P. Valve: PEEP Valve

Classification Name: Dispo – Bag Manual Resuscitator:
Device Name: Ventilator, Emergency, Manual (Resuscitator)
Product Code: BTM
Regulation: 868.5915
Device Class: 2

Disposable PEEP Valve:
Device Name: Attachment, Breathing, Positive End Expiratory Pressure
Product Code: BYE
Regulation: 868.5965
Device Class: 2

Device: Dispo-Bag Manual Resuscitator
Dispo-Bag Manual Resuscitator with Disposable PEEP Valve
Disposable PEEP Valve

Predicate Devices:

Ventilator, Emergency, Manual (Resuscitator):

K944301: Hudson RCI, Temecula, CA (Teleflex Medical, Research Triangle Park, NC); LIFESAVER® Single patient use Manual Resuscitators; Cat. Nos. 5360, 5361, 5362, 5364, 5365, 5366, 5367, 5369, 5370, 5371, 5372, 5373, 5377, 5380, 5387, and 5389.

Attachment, Breathing, Positive End Expiratory:

K902062: Hudson RCI, Temecula, CA (Teleflex Medical, Research Triangle Park, NC); LIFESAVER® PEEP Valve; Cat. Nos. 5383 and 5385.

Device Description:

DISPO-BAG Manual Resuscitation Bags with and without Disposable PEEP Valve:

GaleMed DISPO-BAG Manual Resuscitation Bags are disposable, medical devices which temporarily augment ventilation in patients during ventilatory insufficiency or ventilatory failure.

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GaleMed DISPO-BAG Manual Resuscitation Bags use a duck-bill valve in the non-rebreathing valve assembly, attaches the non-rebreathing valve directly onto the ventilation bag and includes an oxygen enrichment (reservoir) system.

GaleMed DISPO-BAG Manual Resuscitation Bags may be used in the hospital, in physician office, outpatient care facilities, extended care facility, home, emergency medical services and patient transport.

GaleMed DISPO-BAG Manual Resuscitation Bags incorporate a number of features, which are designed to allow flexibility in product configuration:

- Adult, child and infant models with and without face mask
- Adult, child and infant models with open and closed oxygen reservoir systems
- Adult, child and infant models with and without a Positive End Expiratory Pressure (P.E.E.P.) device on the expiratory port

Disposable PEEP Valve:

GaleMed Disposable PEEP Valves are disposable medical devices which elevate the pressure in a patient's lungs above atmospheric pressure at the end of exhalation. The GaleMed Disposable PEEP Valve is a, spring actuated valve, which when placed into a circuit provides positive end expiratory pressure for the patient. The valve is provided in two pressure ranges (5-20 cmH₂O and 2.5 – 10 cm H₂O) and several connector sizes which comply to ISO 5356- I "Anesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets". Likewise the GaleMed single patient use fixed value PEEP valve is a, spring actuated valve, which when placed into a circuit provides positive end expiratory pressure for the patient. The valve is provided in two pressure settings of 2.4, 5.0, 7.5 and 10.0 cmH₂O also offered in several connector sizes which comply to ISO 5356- I "Anesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets".

GaleMed Disposable PEEP Valves may be used in the hospital, extended care facility, emergency medical services and patient transport. They may be used in a constant or intermittent flow system such as resuscitation bags or continuous gas flow systems.

GaleMed Disposable PEEP Valve configurations include:

- 2.5 – 10.0 cm H₂O Adjustable Valve
- 5.0 – 20.0 cm H₂O Adjustable Valve
- Fixed Valves at 2.5, 5.0, 7.5 and 10 cm H₂O

Indications for Use:

DISPO-BAG Manual Resuscitation Bag:

Single patient use manual resuscitator for use hospital, transport, emergency, and post hospital care to temporary ventilate a patient for the given body mass ranges of:

Infant: ≤ 10 Kg, Child: ≤ 23 Kg, Adult: > 23 Kg

DISPO-BAG Manual Resuscitation Bag with Disposable PEEP Valve:

Single patient use manual resuscitator for use hospital, transport, emergency, and post hospital care to temporary ventilate a patient for the given body mass ranges of:

Infant: ≤ 10 Kg, Child: ≤ 23 Kg, Adult: > 23 Kg

This manual resuscitator is supplied with a single patient use positive end expiratory pressure (PEEP) valve for use hospital, transport, emergency, and post hospital care to evaluate end lung pressure above atmospheric at the end of exhalation in constant and intermittent gas flow conditions.

Disposable PEEP Valve:

Single patient use device for use hospital, transport, emergency, and post hospital care for the elevation of lung pressure above atmospheric pressure at the end of exhalation.

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Contraindications:

DISPO-BAG Manual Resuscitation Bag:

Contraindicated in individuals with a body mass of:

Infant: > 10 Kg, Child: > 23 Kg, Adult: < 23 Kg

DISPO-BAG Manual Resuscitation Bag with Disposable PEEP Valve:

Contraindicated in individuals with a body mass of:

Infant: > 10 Kg, Child: > 23 Kg, Adult: < 23 Kg

Contraindicated in individuals not requiring elevation of lung pressure above atmospheric at the end of exhalation.

Disposable PEEP Valve:

Contraindicated in individuals not requiring elevation of lung pressure above atmospheric at the end of exhalation.

Patient Population:

DISPO-BAG Manual Resuscitation Bag:

Patient populations from infant (neonate) to adult.

DISPO-BAG Manual Resuscitation Bag with Disposable PEEP Valve:

Patient populations from infant (neonate) to adult.

Disposable PEEP Valve:

Patient populations from infant (neonate) to adult.

Environment of Use:

DISPO-BAG Manual Resuscitation Bag:

Hospital, transport, emergency, and post hospital care environments.

DISPO-BAG Manual Resuscitation Bag with Disposable PEEP Valve:

Hospital, transport, emergency, and post hospital care environments.

Disposable PEEP Valve:

Hospital, transport, emergency, and post hospital care environments.

Comparative of Technological Characteristics:

DISPO-BAG Manual Resuscitation Bags with and without Disposable PEEP Valve:

GaleMed DISPO-BAG Manual Resuscitation Bags are substantially equivalent in indication for use, environment of use, patient population, design, material and function to the identified predicates.

GaleMed DISPO-BAG Manual Resuscitation Bags and the predicate device use a duck-bill valve in the non-rebreathing valve assembly attach the non-rebreathing valve directly onto the ventilation bag and include an oxygen enrichment (reservoir) system.

GaleMed DISPO-BAG Manual Resuscitation Bags and the predicate device meet the requirements set forth ISO 10651-4:2002 entitled "Lung ventilators - Part 4: Particular requirements for operator powered resuscitators" and ISO 5356-1:2004 entitled "Anaesthetic and respiratory equipment - Conical connectors: Part 1: Cones and sockets".

Disposable PEEP Valves:

GaleMed Disposable PEEP Valves are substantially equivalent in indication for use, environment of use, patient population, design, material and function to the identified predicates.

GaleMed Disposable PEEP Valves and the predicate device meet the requirements set forth ISO 5356-1:2004 entitled "Anaesthetic and respiratory equipment - Conical connectors: Part 1: Cones and sockets". Bench testing confirmed the accuracy of the devices.

Conclusion:

The GaleMed DISPO-BAG Manual Resuscitation Bag, DISPO-BAG Manual Resuscitation Bag with Disposable PEEP Valve and Disposable PEEP Valve are substantially equivalent to the predicate device. Both have similar design characteristics, ventilate in the same manner and have substantially equivalent performance. GaleMed and the predicate devices are made from identical material, have the same intended use and are used in identical environments.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 2008

GaleMed Corporation
C/O Mr. Thomas C. Loescher
President
A Plus Medical
5431 Avenida Encinas, Suite G
Carlsbad, California 92008-4411

Re: K082092

Trade/Device Name: DISPO-BAG Manual Resuscitation Bag
Disposable PEEP Valve
DISPO-BAG Manual Resuscitation Bag with Disposable PEEP
Valve

Regulation Number: 21 CFR 868.5915

Regulation Name: Manual Emergency Ventilator

Regulatory Class: II

Product Code: BTM, BYE

Dated: October 1, 2008

Received: October 2, 2008

Dear Mr. Loescher:

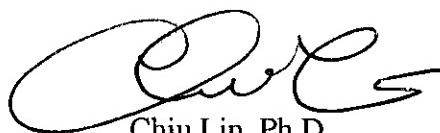
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: KO82092

Device Name: DISPO- BAG Manual Resuscitation Bag

Indications for Use: Single patient use manual resuscitator for use hospital, transport, emergency, and post hospital care to temporary ventilate a patient for the given body mass ranges of:

Infant: ≤ 10 Kg, Child: ≤ 23 Kg, Adult: > 23 Kg

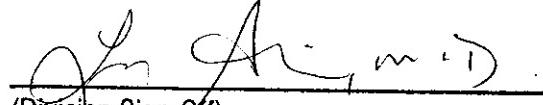
Prescription Use
(Part 21 CFR 801 Subpart D)

or

Over-the-counter use
(21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: KO82092

Indications for Use Statement

510(k) Number: KO82092

Device Name: DISPO- BAG Manual Resuscitation Bag with Disposable PEEP Valve

Indications for Use: Single patient use manual resuscitator for use hospital, transport, emergency, and post hospital care to temporary ventilate a patient for the given body mass ranges of:

Infant: ≤ 10 Kg, Child: ≤ 23 Kg, Adult: > 23 Kg

This manual resuscitator is supplied with a single patient use positive end expiratory pressure (PEEP) valve for use hospital, transport, emergency, and post hospital care to evaluate end lung pressure above atmospheric at the end of exhalation in constant and intermittent gas flow conditions.

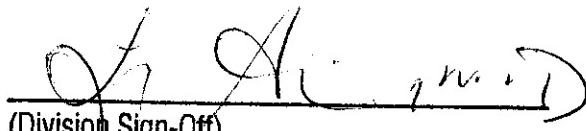
Prescription Use
(Part 21 CFR 801 Subpart D)

or

Over-the-counter use
(21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: KO82092

Indications for Use Statement

510(k) Number: KO82092

Device Name: Disposable PEEP Valve

Indications for Use: Single patient use positive end expiratory pressure (PEEP) valve for use hospital, transport, emergency, and post hospital care to evaluate end lung pressure above atmospheric at the end of exhalation in constant and intermittent gas flow conditions.

Prescription Use
(Part 21 CFR 801 Subpart D)

or

Over-the-counter use
(21 CFR 807 Subpart C)

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